



Massachusetts  
Diabetes  
Prevention & Control Program  
Department of Public Health



JUNE 2011

## MASSACHUSETTS ADULT DIABETES GUIDELINES:

*2011 Executive Summary of Revisions and Recommendations*

DIABETES GUIDELINES WORK GROUP

### Massachusetts Department of Public Health

Developed 1999

Revised 2001, 2003, 2005, 2007, 2009, 2011

This program was partially funded by a cooperative agreement between the Centers for Disease Control and Prevention, Division of Diabetes Translation, and the Massachusetts Department of Public Health, Diabetes Prevention and Control Program.



# DIABETES GUIDELINES WORK GROUP

## DEAR COLLEAGUE:

The Diabetes Prevention and Control Program of the Massachusetts Department of Public Health and members of the Diabetes Guidelines Work Group are pleased to present the latest update to the *Massachusetts Guidelines for Adult Diabetes Care*.

First created in 1999, the *Guidelines* are based on the Clinical Practice Recommendations of the American Diabetes Association (ADA), and are revised every two years. Our initial goals were to: 1) develop uniform guidelines that apply to adults with diabetes regardless of insurer; 2) help eliminate any confusion brought about by differences in guidelines disseminated by individual third party payers; and 3) assist health care professionals in systematizing the care provided to people with diabetes. It has always been our goal to create a document that is user-friendly and which would serve as a valuable tool to improve diabetes care in the Commonwealth. Over time, we've received feedback about making the *Guidelines* even more accessible and user-friendly. This feedback, in addition to the limited number of revisions necessary in the past two years, has prompted a change to the format of the 2011 document.

The *Massachusetts Adult Diabetes Guidelines: 2011 Executive Summary of Revisions and Recommendations (2011 Executive Summary)* is intended to serve as an amendment to the *2009 Massachusetts Guidelines for Adult Diabetes Care (2009 Guidelines)*. The *2011 Executive Summary* highlights the key recommendations for each subsection of the *2009 Guidelines*, even in instances where no new recommendations exist. In this way, we hope that this document will serve as a complete but streamlined reference for evidence-based practice recommendations. We invite you to refer to the *2009 Guidelines* for a more extensive review of the literature supporting the existing recommendations.

**We continue to grade evidence for our recommendations and revisions based on the grading system developed by the ADA. The level of supportive evidence is noted in parentheses after each recommendation using the letters A, B, C, or E:**

- (A): Clear evidence from well-conducted, generalizable, randomized controlled trials.
- (B): Supportive evidence from well-conducted cohort studies.
- (C): Supportive evidence from poorly-controlled or uncontrolled studies.
- (E): Expert consensus or clinical experience.

Recommendations with an "A" rating are based on large well-designed clinical trials or well-done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported. Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence.<sup>1</sup>

The *2011 Executive Summary* and the *2009 Guidelines* may be downloaded from the Massachusetts Health Promotion Clearinghouse at: <http://www.maclearinghouse.com/CatalogDiabetes.htm>

The ADA's 2011 Standards of Medical Care in Diabetes are available at:  
[http://care.diabetesjournals.org/content/34/Supplement\\_1/S11.full.pdf+html](http://care.diabetesjournals.org/content/34/Supplement_1/S11.full.pdf+html)

In addition to the *2011 Executive Summary* and the *2009 Guidelines*, the following tools may be ordered or downloaded through the Clearinghouse:

- **GUIDELINES FOR ADULT DIABETES CARE LAMINATED SUMMARY:**

This summary of the *Guidelines* highlights basic medical care for people with diabetes. We suggest you post a summary in each exam room as a reminder of recommendations for care.

- **DIABETES CARE CARD (PATIENT WALLET CARD):**

The Diabetes Care Card allows people to track their diabetes care and personal goals. The wallet card has space to record test results and services received over four visits. Encourage your patients to bring this card to each office appointment.

- **DETERMINING BODY MASS INDEX (BMI):**

Obesity substantially raises the risk of morbidity from type 2 diabetes and other diseases. The BMI describes relative weight for height and is significantly correlated with total body fat content. The BMI may be used to assess overweight and obesity and to monitor changes in body weight. <http://www.maclearinghouse.com/CatalogDiabetes.htm>

- **FLOW SHEET FOR DIABETES CARE:**

The flow sheet reflects the recommendations found on the *Guidelines for Adult Diabetes Care* laminated summary. It may be downloaded for use in your practice and included in patients' charts. Diabetes medications, exams, and test results can be documented over time to track diabetes management. <http://www.maclearinghouse.com/CatalogDiabetes.htm>

The *2011 Executive Summary* has been a cooperative effort among many partners. This unique collaboration eliminates the confusion brought about by slight differences in guidelines developed by each managed care organization. This document is not intended to serve as a description of benefits or coverage; coverage may vary by insurer. We would like to take this opportunity to acknowledge the partners involved in the development of the *2011 Executive Summary*:

- Baystate Health
- Blue Cross Blue Shield of Massachusetts
- Boston Medical Center HealthNet Plan
- Fallon Community Health Plan
- Harvard Pilgrim Health Care
- Health New England
- Joslin Diabetes Center
- Massachusetts College of Pharmacy and Health Sciences
- Massachusetts Department of Public Health
- Massachusetts League of Community Health Centers
- Massachusetts Medical Society
- Masspro
- Neighborhood Health Plan
- Network Health
- Partners/MGH
- Primary Care Clinician (PCC) Plan
- Tufts Health Plan
- University of Massachusetts, Amherst

If you have questions about the *2011 Executive Summary* or the *2009 Guidelines*, please call the Massachusetts Diabetes Prevention and Control Program at (617) 624–5070. We invite you to join our efforts to reduce the burden of diabetes in Massachusetts by reviewing the *2011 Executive Summary* and applying the key recommendations to your practice.

Sincerely,

**John Auerbach**

Commissioner  
Massachusetts Department of Public Health

**Evan Benjamin, MD**

Vice President of Health Care Quality  
Baystate Health

**Stuart R. Chipkin, MD, FACE**

Research Professor  
School of Public Health and Health Sciences  
University of Massachusetts, Amherst

**Hollis S. Coblentz, DO**

Associate Medical Director  
Fallon Community Health Plan

**Thomas H. Ebert, MD**

Vice President and Chief Medical Officer  
Health New England

**Jennifer D. Goldman-Levine, PharmD, CDE, BC-ADM**

Professor of Pharmacy Practice  
Massachusetts College of Pharmacy and Health Sciences

**Stanley Hochberg, MD**

Chief Medical Officer  
Boston Medical Center HealthNet Plan

**Paul Kasuba, MD**

Senior Vice President, Chief Medical Officer  
Tufts Health Plan

**James Liljestrand, MD, MPH, FACPE**

Medical Performance Improvement Advisor  
MassPRO

**Paul Mendis, MD**

Chief Medical Officer  
Neighborhood Health Plan

**Joan Pernice, RNC, MS**

Director, Clinical Health Affairs  
Massachusetts League of Community Health Centers

**David F. Polakoff, MD, MSc**

Chief Medical Officer  
MassHealth

**Michael Sherman, MD**

Chief Medical Officer  
Harvard Pilgrim Health Care

**Lee Steingisser, MD**

Vice President, Medical Innovation and Leadership  
Blue Cross Blue Shield of Massachusetts

**Pano Yeracaris, MD, MPH**

Vice President and Chief Medical Officer  
Network Health

**Lynda Young, MD**

President  
Massachusetts Medical Society

I. CRITERIA FOR THE DIAGNOSIS OF DIABETES AND PREDIABETES

The recommendations have been updated to include the use of the A1C test for diagnosing diabetes and prediabetes. In 2010, the American Diabetes Association (ADA) endorsed the recommendation of an international expert committee to include the use of the A1C test to diagnose diabetes, with a threshold of  $\geq 6.5\%$ . The recommendation has also been endorsed with qualifications by the American Association of Clinical Endocrinologists/American College of Endocrinologists, and the Endocrine Society. While the fasting blood sugar remains the preferred diagnostic test for diagnosing diabetes, the two-hour oral glucose tolerance (OGTT) or A1C tests are also acceptable.

The A1C test has several advantages over the fasting plasma glucose (FPG) test, including greater convenience, since fasting is not required, and fewer day-to-day variations. These advantages must be balanced against the A1C test's greater cost and the incomplete correlation between A1C and average glucose in certain individuals; A1C may not be as accurate in non-Caucasian individuals and in patients with certain forms of anemia and hemoglobinopathies. Also, the A1C cut point of  $\geq 6.5\%$  identifies one-third fewer cases of undiagnosed diabetes than a fasting glucose cut point of  $\geq 126$  mg/dl.<sup>2, 3, 4, 5</sup>

Criteria for the Diagnosis of Diabetes and Prediabetes

TEST	DIABETES	PREDIABETES
A1C	$\geq 6.5\%$	5.7–6.4%
FPG	$\geq 126$ mg/dl	100–125 mg/dl
2-h 75 g OGTT	$\geq 200$ mg/dl	140–199 mg/dl
Random plasma glucose	$\geq 200$ mg/dl with classic symptoms of hyperglycemia*	N/A

For a diagnosis of diabetes, results should be confirmed by repeat testing. If two different tests are both above the diagnostic thresholds, the diagnosis of diabetes is confirmed. A confirmatory test is not required when results fall into the prediabetes range.

*\*It is the opinion of the Work Group that patients with random glucose > 200 mg/dl, even if asymptomatic, do not require further diagnostic testing, as long as there are no other mitigating factors that would induce reversible hyperglycemia (e.g., glucocorticoids, and/or recent physiological stress).*

## II. CRITERIA FOR TESTING FOR DIABETES AND PREDIABETES IN ASYMPTOMATIC ADULTS

Although preventive screening is widely recognized as a key component of cost-effective, high-quality health care, screening for diabetes falls short of the U.S. Preventive Services Task Force recommendations. In 2007, only 64% of Massachusetts residents with risk factors for diabetes reported being screened in the last three years.<sup>6</sup>

Periodic screening of high-risk individuals as part of ongoing medical care will identify people with undiagnosed diabetes and prevent diabetes-related complications through earlier treatment.

### Criteria for Testing for Diabetes and Prediabetes in Asymptomatic Adults

Testing to detect type 2 diabetes and assess risk for future diabetes in asymptomatic people should be considered in adults of any age who are overweight or obese (BMI  $\geq 25$  kg/m<sup>2</sup> or BMI  $\geq 23$  kg/m<sup>2</sup> for Asian individuals) AND who have one or more of the following additional risk factors for diabetes:

- Habitually physically inactive
- First-degree relative with type 2 diabetes
- Members of a high-risk ethnic population (African American, Latino, Native American, Asian American, Pacific Islander)
- Women who have delivered a baby weighing > 9 lbs. or have been diagnosed with gestational diabetes mellitus (GDM)
- Hypertension (blood pressure  $\geq 140/90$  mmHg, or on therapy for hypertension)
- High-density lipoprotein (HDL) cholesterol level  $\leq 35$  mg/dl and/or a triglyceride level  $\geq 250$  mg/dl
- Polycystic ovarian syndrome (PCOS)
- A1C  $\geq 5.7\%$ , Impaired Glucose Tolerance (IGT) or Impaired Fasting Glucose (IFG) on previous testing
- Other conditions associated with insulin resistance (e.g., acanthosis nigricans)
- History of vascular disease
- A waist circumference > 102 cm (40") for men and > 88 cm (35") for women
- Medication use that may predispose to diabetes (e.g., steroids, atypical antipsychotics, protease inhibitors)

If results are normal, testing should be repeated at three-year intervals, with more frequent testing depending on initial results and risk status.

In those individuals without these risk factors, testing should begin at age 45 years. (B)

### III. CLASSIFICATION OF DIABETES

#### GESTATIONAL DIABETES MELLITUS

Women identified with undiagnosed type 2 diabetes at the initial prenatal visit, using standard diagnostic criteria (FPG, 2-hour 75 g OGTT, or A1C), should receive a diagnosis of type 2 diabetes, not gestational diabetes.

#### PREDIABETES

In addition to IFG (FPG 100–125 mg/dl) and IGT (2-hr 75 g OGTT 140–199 mg/dl), an A1C range of 5.7–6.4% has been included as a category of increased risk for future diabetes.

### IV. PREVENTION OR DELAY OF TYPE 2 DIABETES

Recommendations have been updated to include individuals with an A1C between 5.7 and 6.4% in the at-risk group and to consider metformin for individuals at highest risk for developing diabetes, such as those with multiple risk factors, especially if they demonstrate progression of hyperglycemia.

The Centers for Disease Control and Prevention (CDC) established the National Diabetes Prevention Program to provide training, program recognition, implementation support, and marketing for community-based lifestyle intervention programs for preventing type 2 diabetes: [http://www.cdc.gov/diabetes/projects/prevention\\_program.htm](http://www.cdc.gov/diabetes/projects/prevention_program.htm).

### Recommendations for the Prevention or Delay of Type 2 Diabetes

- Patients with IGT (A), IFG (E), or an A1C 5.7–6.4% (E) should be referred to an effective ongoing support program to achieve a 7% weight loss and for increasing physical activity to at least 150 minutes per week of moderate activity such as walking.
- Follow-up counseling appears to be important for success. (B)
- In addition to lifestyle counseling, metformin may be considered in those individuals at highest risk for developing diabetes, such as those with multiple risk factors, especially if they demonstrate progression of hyperglycemia (i.e., A1C  $\geq$  6%) despite lifestyle interventions. (B)
- Monitoring for the development of diabetes in those individuals with prediabetes should be performed every year. (E)

## V. TREATMENT APPROACH PRINCIPLES

No changes have been made to the recommendations for glycemic goals.

### Recommendations for Glycemic Goals

- Perform the A1C test at least two times a year in patients who are meeting treatment goals and who have stable glycemic control. (E)
- Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals. (E)

### Points to Remember When Setting Glycemic Goals

- A lower A1C is associated with lower rates of microvascular complications; however, there is a greater risk of hypoglycemia. For patients with frequent or severe hypoglycemia, less intensive glycemic control may be preferable.
- If preprandial glucose goals are within target, but A1C values are still not optimal, target postprandial glucose.
- Children, pregnant women, and elderly individuals require special consideration when setting glycemic goals.
- Avoid rapid decline in glycemia when prior adverse control was substantial or prolonged.

Optimal glycemic control is fundamental to the management of diabetes. In addition to lifestyle management, pharmacologic therapy is necessary for most people with type 2 diabetes to achieve glycemic goals. An A1C goal of < 7% is reasonable for many non-pregnant adults. When setting treatment goals for individuals with type 2 diabetes, it is important to assess the risk for severe hypoglycemia and consider the person's ability to comprehend the regimen.

Consider as well other factors that may influence the treatment's benefit, including advanced age, end-stage renal disease (ESRD), advanced cardiovascular or cerebrovascular disease, or other comorbidities that may lead to a reduced life span.



## VI. DIABETES SELF-MANAGEMENT EDUCATION (DSME) AND MEDICAL NUTRITION THERAPY (MNT)

No changes have been made to the recommendations for DSME and MNT.

### Recommendations for Diabetes Self-Management Education

People with diabetes should receive DSME according to national standards at the time of diagnosis and as needed thereafter. (B)

### Recommendations for Medical Nutrition Therapy

- Individuals with prediabetes or diabetes should receive individualized MNT as needed to achieve treatment goals. (B)
- Weight loss is recommended for all overweight or obese individuals who have or who are at risk for diabetes. (A)
- For weight loss, either low-carbohydrate or low-fat, calorie-restricted diets may be effective in the short term (up to one year). (A)
- For patients on low-carbohydrate diets, monitor lipid profiles, renal function, and protein intake (in those with nephropathy) and adjust hypoglycemic therapy as needed. (E)

Although both DSME and MNT have been demonstrated to improve glycemia and CVD risk,<sup>7, 8, 9</sup> these services remain underutilized. The overall objectives of DSME are to support informed decision-making, self-care behaviors, problem-solving, and active collaboration with the health care team to improve clinical outcomes.

DSME is a specialized session of classes designed to help people with diabetes successfully manage their disease. DSME consists of 10 hours of initial training from an accredited education program and an additional two hours of follow-up training each year thereafter with a prescription from a health care provider. National standards regarding what is included in DSME classes are defined by the American

Diabetes Association (ADA) and the American Association of Diabetes Educators (AADE).<sup>10, 11</sup>

MNT is provided by a registered dietitian and is distinct from DSME. MNT involves the development of a personalized healthy eating plan for individuals with prediabetes and diabetes. It includes an in-depth nutrition assessment and nutrition counseling with a focus on achieving positive outcomes for normalizing A1C, serum lipids, and blood pressure. MNT consists of three hours of one-on-one counseling services the first year, and two hours each year thereafter with the possibility of additional hours of treatment with a physician's referral.<sup>12</sup>

## VII. PHYSICAL ACTIVITY

No changes have been made to the recommendations for physical activity.

### Recommendations for Physical Activity

- People with diabetes should be advised to perform at least 150 minutes/week of physical activity (50–70% of maximum heart rate). (A)
- In the absence of contraindications, people with type 2 diabetes should be encouraged to perform resistance training three times per week; targeting all major muscle groups. (A)

People should be encouraged to be more active. Some physical activity is better than none and adults who participate in any amount of physical activity gain some health benefits. Even if patients are not able to meet the physical activity recommendations above, mild to

moderate activity should be encouraged at all levels and abilities. This can be accomplished by building activity into the daily routine, such as using stairs rather than an elevator, and by slowly increasing the amount of time engaged in physical activity.

## VIII. PHARMACOLOGICAL THERAPY

There are a number of pharmacologic agents and strategies that can be employed to reach treatment goals. Emphasis should be on modalities of therapy that have been demonstrated to reduce morbidity and prolong life. When choosing therapy, as long as treatment goals can be reached with safe and effective options, it is less important what those therapies are. The decision of which agent to use

should depend on the degree of A1C-lowering desired and the expected decline in A1C for each class of medication, as well as the effects of the medication on weight and lipid profiles, contraindications, side effects, cost, and potential degree of adherence to the regimen (*See Table of Commonly Used Anti-hyperglycemic Agents: <http://www.maclearringhouse.com/CatalogDiabetes.htm>*).

## IX. CARDIOVASCULAR RISK-REDUCTION GUIDELINES

Cardiovascular disease (CVD) is the major cause of morbidity and mortality for people with diabetes. Hypertension and dyslipidemia, common coexisting conditions, are clear risk factors for CVD and diabetes itself confers independent risk.

Controlling individual cardiovascular risk factors is a major component of the prevention and management of CVD in people with diabetes.

## A. HYPERTENSION

Recommendations for control of hypertension have been revised to reflect new evidence reinforcing the importance of individualization of blood pressure goals. The ACCORD Blood Pressure Trial evaluated the effect of targeting a systolic blood pressure of 120 mmHg, as compared with a goal of 140 mmHg, among patients with type 2 diabetes at high risk for cardiovascular events.

The results provide no evidence that the strategy of intensive blood pressure control reduces the rate of a composite outcome of fatal and nonfatal major cardiovascular events. Additionally, the rate of serious adverse effects of treatment such as hypotension and hyperkalemia were significantly higher in the intensive control group.<sup>14</sup>

### Recommendations for Controlling Hypertension

- A goal systolic blood pressure (SBP) < 130 mmHg is appropriate for most patients with diabetes. (C)  
Based on patient characteristics and response to therapy, higher or lower systolic blood pressure targets may be appropriate. (B)
- Patients with diabetes should be treated to a diastolic blood pressure (DBP) < 80 mmHg. (B)
- Patients with SBP of 130–139 mmHg or DBP of 80–89 mmHg may be given lifestyle therapy alone for a maximum of three months and then, if targets are not achieved, be treated with the addition of pharmacological agents. (E)
- Patients with more severe hypertension (SBP ≥ 140 mmHg or DBP ≥ 90 mmHg) at diagnosis or follow-up should receive prescriptions for both antihypertensive medication and lifestyle/behavioral changes. (A)
- All patients with diabetes and hypertension should be treated with angiotensin-converting enzyme (ACE) inhibitors. If ACE inhibitors are not tolerated, an angiotensin II receptor blocker (ARB) should be considered, if not contraindicated. Add a thiazide diuretic in those with estimated GFR ≥ 30 ml/min per 1.73 m<sup>2</sup> or a loop diuretic for those with estimated GFR < 30 ml/min per 1.73 m<sup>2</sup> if needed to reach target blood pressure. (C)
- Monitor renal function and serum potassium levels when using ACE inhibitors, ARBs, or diuretics. (E)
- Multiple drug therapy utilizing two or more agents at proper doses is often necessary to reach target levels. (A)
- Clinical trials provide evidence that ACE inhibitors and ARBs have an additional impact on nephropathy and CVD. (A)
- Beta-blockers should be added for those who have had a recent myocardial infarction (MI) if not contraindicated; caution should be used in those with hypoglycemia unawareness. (A)
- In pregnant patients with diabetes and chronic hypertension, target blood pressure goals of 110–129/65–79 mmHg are suggested. ACE inhibitors and ARBs are contraindicated during pregnancy and should be discontinued in women planning pregnancy due to their teratogenic effects. (E)

## B. DYSLIPIDEMIA/LIPID MANAGEMENT

The recommendations have been revised to include the addition of omega-3 fatty acids, viscous fiber, and plant sterols to lifestyle modifications.

The ACCORD lipid arm, in which adults with type 2 diabetes at high risk for cardiovascular events were given either statin monotherapy or combination therapy of statin plus fibrate found select subgroups of patients who benefitted from combination therapy. However, the overall risk of heart attack, stroke, or death from cardiovascular disease was not lower than treatment with statins alone.

At this time, the FDA has made no new conclusions or recommendations regarding the combination use of simvastatin or other statin drugs and fenofibrate.<sup>15</sup>

The FDA is recommending limiting the use of simvastatin (80 mg) because of increased risk of muscle damage. Simvastatin 80 mg should be used only in patients who have been taking this dose for 12 months or more without evidence of muscle injury (myopathy). Simvastatin 80 mg should not be started in new patients, including patients already taking lower doses of the drug.<sup>16</sup>

### Recommendations for Dyslipidemia/Lipid Management

- In most adult patients, measure fasting test for lipid disorders at least annually with more frequent testing as necessary to reach goal levels. (E)
- Testing every two years is adequate for those with low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides (TG) within the target levels. (E)
- Lifestyle modification with MNT focusing on reduction of saturated fat, *trans* fat, and cholesterol intake; increased intake of foods rich in omega-3 fatty acids, viscous fiber, and plant sterols;\* weight loss (if indicated); and increased physical activity should be recommended to improve lipid profile. (A)
- Statin therapy should be added to lifestyle therapy, regardless of baseline lipid levels, for patients with diabetes with overt CVD (A) and for patients without CVD who are over the age of 40 and have one or more other CVD risk factors. (A)
- In patients without overt CVD and under age 40, or those with multiple CVD risk factors, statin therapy should be considered in addition to lifestyle therapy if LDL cholesterol remains above 100 mg/dl. (E)
- In individuals without overt CVD, the primary goal is an LDL cholesterol of < 100 mg/dl. (A)
- In individuals with overt CVD, a lower LDL cholesterol goal of < 70 mg/dl, using a high dose of a statin, is an option. (B)
- If patients treated with drugs do not reach targets on maximal tolerated statin therapy, a reduction in LDL cholesterol of ~30–40% from baseline is an alternative therapeutic goal. (A)
- Triglyceride levels < 150 mg/dl and HDL cholesterol > 40 mg/dl in men and > 50 mg/dl in women are desirable. However, LDL cholesterol-targeted statin therapy remains the preferred strategy. (C)
- Statin therapy is contraindicated in pregnancy. (E)

\* Omega-3 fatty acids are usually found in seafood, such as salmon, herring, sardines, and mackerel. They can also be found in flaxseeds, flaxseed oil, and walnuts.

\* Examples of soluble or viscous fibers include oat bran, oatmeal, beans, peas, rice bran, barley, citrus fruits, strawberries, and apple pulp.

\* Plant sterols are naturally found in fruits, vegetables, whole grains, legumes, nuts, and seeds.

### C. ANTIPLATELET THERAPY

This section has been revised to reflect recent trials that question the benefit of aspirin therapy for primary cardiovascular disease prevention in moderate- or low-risk patients. The recommendation has been changed to consider aspirin therapy as a primary prevention strategy in individuals with

diabetes who are at increased cardiovascular risk (10-year risk > 10%). This includes most men over age 50 and most women over age 60 who have at least one additional risk factor (family history of CVD, hypertension, smoking, dyslipidemia, and/or albuminuria).

## Recommendations for Antiplatelet Therapy

- Use aspirin therapy (75-162 mg/day) as a secondary prevention strategy in men and women with diabetes and a history of myocardial infarction, vascular bypass procedure, stroke or transient ischemic attack, peripheral vascular disease, claudication, and/or angina. (A)
- Consider aspirin therapy (75-162 mg/day) as a primary prevention strategy in men and women with type 1 or type 2 diabetes at increased cardiovascular risk (10-year risk > 10%). This includes most men over 50 years of age or most women over 60 years of age who have at least one additional risk factor (family history of CVD, hypertension, smoking, dyslipidemia, albuminuria). (C)
- Aspirin should not be recommended for CVD prevention for adults with diabetes who are at low CVD risk (10-year CVD risk < 5%), men under 50 years of age and women under 60 years of age with no additional risk factors. For patients in these age groups with multiple other risk factors (i.e., 10-year CVD risk 5-10%), clinical judgment should guide treatment decisions. (C)
- People with aspirin allergy, bleeding tendency, recent gastrointestinal bleeding, and clinically active hepatic disease are not candidates for aspirin therapy. Other antiplatelet agents, such as clopidogrel, may be a reasonable alternative for high-risk patients with contraindications to aspirin therapy. (B)
- Combination therapy with aspirin (75-162 mg/day) and clopidogrel (75 mg/day) is reasonable for up to a year after an acute coronary syndrome. (B)

## D. CORONARY HEART DISEASE

In patients with prior myocardial infarction, recommendations on the use of beta-blockers have been revised. Continuation of beta-blockers for at least two years after the event is recommended, and the level of evidence has been changed from level A to level B.

Longer term use of beta-blockers in the absence of hypertension is reasonable if well tolerated, however data are lacking. The recommendation for coronary artery disease (CAD) screening in asymptomatic patients has also been revised.

### Recommendations for Coronary Heart Disease Screening and Treatment

- In patients with known CVD: angiotensin-converting enzyme (ACE) inhibitor (C), aspirin (A), and statin therapy (if not contraindicated) (A), should be used to reduce the risk of cardiovascular events.
- In patients > 40 years of age with another cardiovascular risk factor (hypertension, premature family history, dyslipidemia, microalbuminuria, cardiac autonomic neuropathy, or smoking), aspirin and statin therapy (if not contraindicated) should be used to reduce the risk of cardiovascular events. (B)
- A beta-blocker, if not contraindicated, should be added for at least two years for patients with a prior myocardial infarction. (B)
- Longer term use of beta-blockers in the absence of hypertension is reasonable if well tolerated, however data are lacking. (E)
- Screening tests such as a stress electrocardiogram (ECG), and/or stress echocardiography, and/or perfusion imaging may be beneficial for those with:
  - 1) typical or atypical cardiac symptoms, and/or
  - 2) an abnormal resting electrocardiogram. (E)
- In asymptomatic patients, routine screening for CAD is not recommended as it does not improve outcomes as long as CVD risk factors are treated. (A)

## X. SMOKING CESSATION

No changes have been made to the recommendations for smoking cessation.

### Recommendations for Smoking Cessation

- Advise all patients not to smoke. (A)
- Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care. (B)

QuitWorks is a free smoking cessation referral service available to all Massachusetts health care providers that links patients who use tobacco to the evidence-based tobacco treatment services offered by the Massachusetts Smokers' Helpline ([www.quitworks.org](http://www.quitworks.org)).

Referring providers receive reports from QuitWorks on the Helpline services each patient selects and their subsequent quit status.

XI. NEPHROPATHY

No changes have been made to the recommendations for nephropathy screening. This section has been updated to include a table of screening and treatment recommendations for renal disease.

Recommendations for Nephropathy Screening

- Type 2 diabetes: assess urine albumin excretion at diagnosis and yearly thereafter. (E)
- Type 1 diabetes: assess urine albumin excretion after five years of disease duration and yearly thereafter. (E)
- Serum creatinine should be measured annually in all adults with diabetes for the estimation of glomerular filtration rate (GFR) and to stage the level of chronic kidney disease. (E)

Stages of Kidney Disease<sup>17</sup>

STAGE	DESCRIPTION	GFR (ml/min per 1.73 m <sup>2</sup> body surface area)
1	Kidney damage* with normal or increased GFR	> 90
2	Kidney damage* with mildly decreased GFR	60–89
3	Moderately decreased GFR	30–59
4	Severely decreased GFR	15–29
5	Kidney Failure	< 15 or dialysis

\* Kidney damage is defined as abnormalities on pathologic, urine, blood or imaging tests



## Management of Chronic Kidney Disease in Diabetes<sup>18</sup>

GFR (ml/min/1.73 m <sup>2</sup> )	RECOMMENDED
<b>All patients</b>	Yearly measurement of creatinine, urinary albumin excretion, potassium
<b>GFR 45–60</b>	<ul style="list-style-type: none"> <li>• Referral to nephrology if possibility for nondiabetic kidney disease exists (duration type 1 diabetes &lt; 10 years, heavy proteinuria, abnormal findings on renal ultrasound, resistant hypertension, rapid fall in GFR, or active urinary sediment)</li> <li>• Consider need for dose adjustment of medications</li> <li>• Monitor estimated GFR (eGFR) every six months</li> <li>• Monitor electrolytes, bicarbonate, hemoglobin, calcium, phosphorus, and parathyroid hormone at least yearly</li> <li>• Assure vitamin D sufficiency</li> <li>• Consider bone density testing</li> <li>• Referral for dietary counseling</li> </ul>
<b>GFR 30–44</b>	<ul style="list-style-type: none"> <li>• Referral to nephrology if possibility for nondiabetic kidney disease exists (duration type 1 diabetes &lt; 10 years, heavy proteinuria, abnormal findings on renal ultrasound, resistant hypertension, rapid fall in GFR, or active urinary sediment)</li> <li>• Consider referral to nephrologist if unable to achieve targets</li> <li>• Assure vitamin D sufficiency</li> <li>• Consider bone density testing</li> <li>• Consider need for dose adjustment of medications</li> <li>• Referral for dietary counseling</li> <li>• Monitor eGFR every three months</li> <li>• Monitor electrolytes, bicarbonate, calcium, phosphorus, parathyroid hormone, hemoglobin, albumin, and weight every three to six months</li> <li>• Consider need for dose adjustment of medications</li> </ul>
<b>GFR &lt; 30</b>	Referral to nephrologist

*Adapted from the ADA Standards of Medical Care in Diabetes — 2011*

Microalbuminuria, a low but abnormal level of albumin in the urine, is a risk factor for diabetes-related renal and cardiovascular complications. Studies have demonstrated that multifactorial interventions, including pharmacological management of hyperglycemia, hypertension, and

dyslipidemia, can reduce progression of albuminuria, retinopathy, neuropathy, and composite outcomes of CVD events or death.<sup>19</sup> Continued annual monitoring of urine albumin excretion is recommended to assess response to therapy and progression of disease.

## XII. RETINOPATHY

No changes have been made to the recommendations for retinopathy screening and treatment.

### Recommendations for Retinopathy Screening and Treatment

- An ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management should perform comprehensive eye exams. (E)
- Adults with type 1 diabetes should have an initial dilated and comprehensive eye examination within five years of the diagnosis of diabetes. (B)
- Adults with type 2 diabetes should have an initial dilated and comprehensive eye examination shortly following the diagnosis of diabetes. (B)
- Subsequent examinations for patients with type 1 and type 2 diabetes should be repeated annually. A qualified eye care professional may recommend less frequent exams (i.e., every two years). (B)
- Examinations will be required more frequently if retinopathy is progressing. (B)
- Women with preexisting diabetes should have a comprehensive eye exam when planning pregnancy and should be counseled on the risk of development and/or progression of diabetic retinopathy. (B)
- Women with diabetes who become pregnant should have a comprehensive eye exam in the first trimester with close follow-up at intervals determined by retinopathy status throughout pregnancy and for one year postpartum. (B)
- Retinal screening is not necessary for women who develop gestational diabetes because these women are not at increased risk for diabetic retinopathy. (B)
- In general, small doses of aspirin for cardioprotection are safe in patients with retinopathy; when in doubt, consult a diabetic eye disease specialist. (A)
- Anyone with a change or loss of vision requires prompt referral to an eye care specialist. (A)

Diabetic retinopathy is one of the most prevalent but preventable causes of blindness in the U.S. Complications from diabetic retinopathy can be largely prevented by glycemic and blood pressure control, as well as by early detection and timely treatment of diabetic retinopathy. Unfortunately, only about half of all patients with diabetes receive the recommended screening for retinopathy and only 40% of patients who require vision-preserving laser surgery receive it.<sup>20, 21</sup>

Retinal photography may be indicated for examination of the retina in patients with diabetes in whom symptoms of visual disturbances may be present and in whom retinal examination may be unremarkable. However, retinal photography should not replace a comprehensive eye exam. Ocular conditions such as cataracts, hypertensive retinopathy, and glaucoma are optimally evaluated during a comprehensive eye exam.

### XIII. NEUROPATHY

No changes have been made to the recommendations for neuropathy screening. See the *2009 Adult Diabetes Guidelines* for signs and symptoms of autonomic neuropathy and for treatment recommendations.

#### Recommendations for Neuropathy Screening

- Patients with diabetes should be screened for presenting signs and symptoms of diabetic autonomic neuropathy as part of the initial history and review of systems. (B)
- Screening for signs and symptoms of cardiovascular autonomic neuropathy should be instituted at diagnosis of type 2 diabetes and five years after the diagnosis of type 1 diabetes. (E)
- Conduct a comprehensive foot exam at least annually. The exam may take place in the primary care setting and should include a visual inspection and palpation for pulses as well as a sensory evaluation using a tuning fork or a Semmes-Weinstein monofilament. (B)
- Perform a visual foot inspection at every visit for patients who have neuropathy. (E)
- Provide self-care education to all patients, especially those with risk factors such as smoking or prior lower extremity complications. (B)
- Refer patients who have loss of protective sensation and structural abnormalities, or who have a prior history of lower-extremity complications, to a podiatrist for ongoing preventive care. (C)
- Screen for peripheral artery disease (PAD) by assessing the pedal pulses and evaluating for a history of claudication. Consider obtaining an ankle-brachial index (ABI), as many patients with PAD are asymptomatic. (C)
- Refer patients with significant claudication or a positive ABI for further vascular assessment. (C)
- Offer a multidisciplinary approach for patients with foot ulcers and high-risk feet. (B)

## XIV. PERIODONTAL DISEASE

No changes have been made to the recommendations for the management of periodontal disease.

### Recommendations for the Management of Periodontal Disease

- Conduct an oral exam as part of the yearly comprehensive visit. (E)
- Advise patients of the importance of oral hygiene. (E)
- Promptly refer patients with symptoms of periodontal disease for dental evaluation. (E)
- Encourage patients to receive dental follow-up twice a year and more often if necessary. (E)
- Encourage patients who smoke to stop. (A)

## XV. IMMUNIZATIONS

No changes have been made to the recommendations for immunizations.

### Recommendations for Immunizations

- Provide an influenza vaccine annually to all patients with diabetes  $\geq 6$  months of age. (C)
- Administer pneumococcal polysaccharide vaccine to all patients with diabetes  $\geq 2$  years of age. A one-time revaccination is recommended for individuals  $\geq 65$  years of age previously immunized when they were  $< 65$  years of age if the vaccine was administered  $> 5$  years ago. Other indications for repeat vaccination include nephrotic syndrome, chronic renal disease, and other immunocompromised states. (C)

In addition to influenza and pneumococcal vaccines, early vaccination against hepatitis B is indicated in patients likely to progress to end-stage kidney disease.

Zoster vaccine was recently recommended by the Advisory Committee on Immunization Practices (ACIP) to reduce the risk of shingles and its associated pain in people  $> 60$  years of age.

## XVI. PSYCHOSOCIAL ASSESSMENT

No changes have been made to the recommendations for psychosocial assessment.

### Recommendations for Psychosocial Assessment

- Incorporate psychological screening and treatment into routine care rather than waiting for identification of a specific problem or deterioration in psychological status. (E)
- Psychosocial screening and follow-up should include, but is not limited to, attitudes about the illness; expectations for medical management and outcomes; affect/mood; general and diabetes-related quality of life; resources (financial, social, and emotional); and psychiatric history. (E)
- Screen for psychosocial problems such as depression, anxiety, eating disorders, and cognitive impairment when adherence to the medical regimen is poor. (E)

It is widely believed that the use of second-generation antipsychotics (SGAs), also commonly known as *atypical* antipsychotics, is associated with an increased risk of diabetes.<sup>22, 23</sup> What is less clear is whether the risk is indirect due to weight gain, or whether the SGAs directly affect insulin secretion or sensitivity.<sup>24</sup> Additionally, different SGAs appear to have different degrees of effect on weight gain and insulin sensitivity.<sup>25</sup>

In 2009, the European Psychiatric Association issued a position statement that while the use of SGAs is clearly associated with an increased risk of diabetes, the risk is small compared to traditional risk factors.<sup>26</sup> Until further evidence is available, the position of the Work Group is that people who take SGAs should be considered to be at increased risk, and screened for diabetes according to standard guidelines.

## XVII. INPATIENT GLUCOSE MANAGEMENT

The recommendations have been revised to include initiation of insulin and target glucose levels for critically ill patients.

### Recommendations for Inpatient Glucose Management

- All hospitalized patients with diabetes should have their diabetes clearly identified in the hospital record. (E)
- All patients with diabetes should have an order for blood glucose monitoring, with results available to all members of the health care team. (E)
- Scheduled prandial insulin doses should be appropriately timed in relation to meals and should be adjusted to point-of-care glucose levels. (C)
- For critically ill patients, insulin therapy should be initiated for treatment of persistent hyperglycemia starting at a threshold of no greater than 180 mg/dl. Once insulin therapy is started, target glucose levels between 140–180 mg/dl for the majority of patients. (A)
- For non-critically ill patients treated with insulin, premeal blood glucose target should be < 140 mg/dl in conjunction with random blood glucose values < 180 mg/dl, provided these targets can be safely achieved. (A)

- <sup>1</sup> American Diabetes Association. Introduction. *Diabetes Care*. 2009;32(suppl 1):S1–S2.
- <sup>2</sup> American Diabetes Association. Standards of medical care in diabetes – 2011 (Position Statement). *Diabetes Care*. 2011;34(suppl 1):S11–S61.
- <sup>3</sup> American Diabetes Association. Diagnosis and classification of diabetes mellitus (Position Statement). *Diabetes Care*. 2010;33(suppl 1):S62–S69.
- <sup>4</sup> American Association of Clinical Endocrinologists Board of Directors and American College of Endocrinologists Board of Trustees. American Association of Clinical Endocrinologists/American College of Endocrinology statement on the use of hemoglobin a1c for the diagnosis of diabetes (Position Statement). *Endocrine Practice*. 2010;16(2):155–156.
- <sup>5</sup> International Expert Committee. International Expert Committee report on the role of the A1C assay in the diagnosis of diabetes. *Diabetes Care*. 2009;32(7):1327–1334.
- <sup>6</sup> Massachusetts Department of Public Health. Massachusetts Behavioral Risk Factor Surveillance System Data; 2007.
- <sup>7</sup> Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care*. 2002;25(7):1159–1171.
- <sup>8</sup> Pastors JG, Warshaw H, Daly A, Franz M, Kulkarni K. The evidence for the effectiveness of medical nutrition therapy in diabetes management. *Diabetes Care*. 2002;25(3):608–613.
- <sup>9</sup> Institute of Medicine. *The role of nutrition in maintaining health in the nation's elderly: Evaluating coverage of nutrition services for the Medicare population*. Washington, DC: National Academy Press; 2000:118–131.
- <sup>10</sup> American Diabetes Association Education Recognition Programs. <http://professional.diabetes.org/Recognition.aspx?cid=57941&typ=15>. Accessed June 1, 2009.
- <sup>11</sup> American Association of Diabetes Educators (AADE) Diabetes Education Accreditation Program. <http://www.diabeteseducator.org/ProfessionalResources/accred/index.html>. Accessed July 13, 2011.
- <sup>12</sup> Centers for Medicare and Medicaid Services. Medical nutrition therapy services: overview. <http://www.cms.hhs.gov/medicalnutritiontherapy>. Updated December 14, 2005. Accessed March 7, 2011.
- <sup>13</sup> U.S. Department of Health and Human Services. 2008 Physical Activity Guidelines for Americans. <http://www.health.gov/paguidelines/guidelines/summary.aspx>. Updated October 16, 2008. Accessed March 7, 2011.
- <sup>14</sup> ACCORD Study Group. Effects of intensive blood-pressure control in type 2 diabetes. *N Engl J Med*. 2010;362(17):1575–1585.
- <sup>15</sup> U.S. Food and Drug Administration. Statement to Healthcare Professionals on the ACCORD Lipid Trial from the FDA's Center for Drug Evaluation and Research. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm203681.htm>. Updated March 15, 2010. Accessed May 5, 2011.
- <sup>16</sup> FDA Drug Safety Communication: New restrictions, contraindications, and dose limitations for Zocor (simvastatin) to reduce the risk of muscle injury. <http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm>. Accessed June 23, 2011.
- <sup>17</sup> American Diabetes Association. Standards of medical care in diabetes – 2009 (Position Statement). *Diabetes Care*. 2009;32(suppl 1):S13–S61.
- <sup>18</sup> American Diabetes Association. Standards of medical care in diabetes – 2011 (Position Statement). *Diabetes Care*. 2011;34(suppl 1):S11–S61.
- <sup>19</sup> Gaede P, Vedel P, Larsen N, Jensen GV, Parving HH, Pedersen O. Multifactorial intervention and cardiovascular disease in patients with type 2 diabetes. *N Engl J Med*. 2003;348(5):383–393.
- <sup>20</sup> Garg S, Davis RM. Diabetic Retinopathy Screening Update. *Clinical Diabetes*. 2009;27(4):140–145.
- <sup>21</sup> Ferris FL 3rd, Davis MD, Aiello LM. Treatment of diabetic retinopathy. *N Engl J Med*. 1999;341(9):667–678.
- <sup>22</sup> American Diabetes Association. Consensus development conference on antipsychotic drugs and obesity (Consensus Statement). *Diabetes Care*. 2004;27(2):596–601.
- <sup>23</sup> Sernyak MJ, Leslie DL, Alarcon RD, Losonczy MF, Rosenheck R. Association of diabetes mellitus with use of atypical neuroleptics in the treatment of schizophrenia. *Am J Psychiatry*. 2002;159(4):561–566.
- <sup>24</sup> De Hert M, Dekker JM, Wood D, Kahl KG, Holt RI, Möller HJ. Cardiovascular disease and diabetes in people with severe mental illness position statement from the European Psychiatric Association (EPA), supported by the European Association for the Study of Diabetes (EASD) and the European Society of Cardiology (ESC). *Eur Psychiatry*. 2009;24(6):412–24.
- <sup>24</sup> American Diabetes Association. Consensus development conference on antipsychotic drugs and obesity (Consensus Statement). *Diabetes Care*. 2004;27(2):596–601.
- <sup>25</sup> De Hert M, Dekker JM, Wood D, Kahl KG, Holt RI, Möller HJ. Cardiovascular disease and diabetes in people with severe mental illness position statement from the European Psychiatric Association (EPA), supported by the European Association for the Study of Diabetes (EASD) and the European Society of Cardiology (ESC). *Eur Psychiatry*. 2009;24(6):412–24.

## 2011 ADULT DIABETES GUIDELINES WORK GROUP MEMBERS

### **Mohamed F. Ally, MD**

Senior Medical Director  
Network Health

### **Lloyd Axelrod, MD**

Physician and Chief of the James Howard Means Firm  
Massachusetts General Hospital  
Associate Professor of Medicine  
Harvard Medical School

### **Joanne Baggerly, PhD, RN**

Manager, Health Programs  
Tufts Health Plan

### **Andrew Balder, MD**

Medical Director  
Boston Medical Center HealthNet Plan

### **Claire Blais, RD, CDE, LDN**

Nutrition Specialist  
Diabetes Prevention and Control Program  
Massachusetts Department of Public Health

### **Melanie J. Brunt, MD, MPH**

Chief of Endocrinology  
Cambridge Health Alliance  
Clinical Instructor in Medicine  
Harvard Medical School

### **Roberta Capelson, MS, ANP**

Manager of Diabetes Outreach  
Boston Medical Center

### **Catherine Carver, MS, APRN, BC, CDE**

Vice President, Clinical Services  
Joslin Diabetes Center

### **Emilie Castro, MPH**

Clinical Guidelines Research Analyst  
Harvard Pilgrim Health Care

### **Stuart Chipkin, MD**

Research Professor  
School of Public Health and Health Sciences  
University of Massachusetts, Amherst  
Medical Advisor  
Diabetes Prevention and Control Program  
Massachusetts Department of Public Health

### **Hollis S. Coblentz, DO**

Associate Medical Director  
Fallon Community Health Plan

### **Patricia Daly, MS, RN**

Health Systems Specialist  
Diabetes Prevention and Control Program  
Massachusetts Department of Public Health

### **Therese Fitzgerald, PhD**

Health Policy Research Director  
Massachusetts Medical Society

### **Jennifer D. Goldman-Levine, PharmD, CDE, BC-ADM**

Professor of Pharmacy Practice  
Massachusetts College of Pharmacy and Health Sciences

### **Joan Hill, RD, CDE, LDN**

Consultant  
Diabetes Prevention and Control Program  
Massachusetts Department of Public Health

### **Richard Kalish, MD, MPH**

Medical Director  
Boston Medical Center HealthNet Plan

### **Marlene Kane, RN, BSN, CPHQ**

Clinical Project Coordinator  
PCC Plan, Quality Management  
Executive Office of Health and Human Services



**Carolyn Langer, MD, JD, MPH**

Medical Director  
Medical Management and Policy  
Harvard Pilgrim Health Care

**James Liljestrand, MD, MPH, FACPE**

Medical Performance Improvement Advisor  
MassPRO

**Paul Mendis, MD**

Chief Medical Officer  
Neighborhood Health Plan

**Terri Grodner Mendoza, MS, RD, LDN**

Director  
Diabetes Prevention and Control Program  
Massachusetts Department of Public Health

**Roger L. Snow, MD, MPH**

Deputy Medical Director  
Office of Clinical Affairs  
MassHealth

**Lee Steingisser, MD**

Vice President, Medical Innovation and Leadership  
Blue Cross Blue Shield of Massachusetts

**Mary B. Thompson, ANP-BC**

Health Programs, Program Manager  
Tufts Health Plan

**Alan R. Titelbaum, O.D.**

Associate Medical Director  
Office of Clinical Affairs  
Executive Office of Health and Human Services

**Deborah Ann Titelbaum, RN, BSN**

Nurse Manager  
MCO Unit; Special Kids/Special Care Program  
Executive Office of Health and Human Services

**Pano Yeracaris, MD, MPH**

Vice President and Chief Medical Officer  
Network Health